REMARKS

This application is amended in a manner believed to place it condition for allowance.

Status of the Claims

Claims 59, 61, 62, 65-69, 73, 75, 77, 79, and 86-89 have been amended.

Claims 63 and 64 are cancelled.

Claims 90-117 have been added.

Claims 59-61 and 64-117 remain pending.

Support for the amended and new claims is as follows:

Claim 59 now includes the features of previously pending claim 63. The new recitation "insertable through the proximal end into the working duct" finds support on page 8, lines 32-33 of the originally filed specification. The direction of insertion has also been specified.

Claims 61 and 62 now depend from new claim 90. Claim 61 includes additional formal amendments, and claim 62 has been amended in a manner consistent with specification page 5, lines 24-30.

Claim 65 now depends from claim 59.

Claim 66 now defines the axial direction with respect to the working duct.

Claim 67 now recites "radially opening nozzles". That is, as the radially opening nozzles are either directed inward or

outward, claim 67 more generally recites "radially opening nozzles". Also, the radial direction is defined with respect to the working duct.

Claim 68 is now dependent from claim 67, as outwardly inclined suction nozzles will have a radial direction component (as well as an axial direction component), the outwardly inclined suction nozzles will also (partly) face in the radial outward direction. Further, the axial direction is now defined with respect to the working duct.

Claim 69 now depends from amended claim 67, and the radial direction is now defined with respect to the working duct.

Claims 73 and 75 correct a typographic error.

Claims 77 and 79 now recite the fixing device as a definite part of the invention.

Claim 86 is amended in a manner similar to claim 59.

Claim 87 is based on former claim 87 and former claim 64, and is further amended in a manner consistent with claim 59.

Claims 88 and 89 are amended in manner similar to claim 59, and has been further amended to recite "mechanically" fixed.

Claim 90 is supported by lines 8-12 of claim 87, which were also part of former claim 87.

Claim 91 is based on the now generalized former claim 67. This claim is the 'radially outward' analogous version of amended claim 69.

Claim 92 is based on former claim 68. As the outwardly inclined suction nozzles will have an axial direction component (as well as a radial direction component), the outwardly inclined suction nozzles will also (partly) face in the axial direction.

Claim 93 is supported by specification page 19, lines 28 and 29.

Claim 94 recites the "fixing device" of claim 60, which is no longer part of the claimed assembly, but the 'fixing device' is now part of the assembly described in claim 93.

Claim 95 adds to claim 93 that the fixing device comprises a heart valve prosthesis. Basis for this can be found on many places throughout the application, for example, on page 26, lines 9-14.

Claim 96 is supported by, for example, page 36, lines 16-26 and page 37, line 27.

Claim 97 is supported by, for example, page 36, lines 16, 18 and 19.

Claim 98 is supported by, for example, figures 18-19.

Claim 99 is supported by, for example, figures 18-19 and figure 34.

Claim 100 is supported by original claim 33.

Claim 101 is supported by, for example, page 55 lines 15-17.

Claim 102 is supported by, for example, page 59, lines 11 and 12.

Claim 103 is supported by, for example, figure 34 (the ref. numbers 616 and 613) and page 58 line 20.

Claim 104 is supported by, for example, figure 34 (the ref. 613) and page 58 line 20.

Claim 105 is directed to the combination of amended claims 59 and 67.

Claim 106 is directed to the combination of amended claims 59 and 65.

Claim 107 defines that the "suction line is operationally separated from the cylindrical lumen delimited by the wall of the working duct". Support may be found, for example, in figure 2, which clearly shows that 4 extends from the suction nozzle 8 upwards to the proximal part of the working duct.

Claim 108 defines that the "a suction passage is formed in the interior of the wall of the working duct, which passage extends from the suction nozzles up to a proximal part of the working duct" Support may be found, for example, on page 19, lines 14-16 and figure 2.

Claim 109 is supported by page 4, lines 18-19 and page 51, lines 3 and 27.

Claim 110 is supported by, for example, figure 34 (parts 607 and 617 are coupled after delivery by assembly) and page 54, line 9 to page 56, line 9.

Claims 111 and 112 are supported by, for example, page 50, lines 28-31 and page 51, lines 2-9.

Claim 113 is supported by, for example, page 52, lines 1-3 and figure 33.

Claim 114 is supported by, for example, page 55, lines 24-29.

Claim 115 is supported by, for example, page 61, lines 2-8.

Claim 116 and 117 are supported by, for example, page 52, lines 10-12.

Amendment to the Specification

Applicant noted a translation error in the English translation of the originally filed application, e.g., WO 03/082121. WO 03/082121 mentions on several places the term 'hilum' (see WO 03/082121 page 1, line 22, page 45, line 3, page 48, line 31, page 51, line 26 and 27, and page 52, line 6) or 'hila' (see WO 03/082121 page 4, line 18).

The PCT application was originally filed in Dutch. In the Dutch text the Dutch term is 'poort'. The correct English translation for this word is 'port'. Therefore the amendment to the specification changes 'hilum' to 'port' and 'hila' to 'ports'.

Claim Objections

The claims were objected to for including informalities.

Amendments have been made to claims 59, 61-63, 65, 70, 72, 73, 82, and 85-89 as suggested in the Official Action.

Therefore, withdrawal of the objection is respectfully requested.

Claim Rejections-35 USC §112

Claims 77-79 were rejected under 35 USC §112, second paragraph, as being indefinite. This rejection is respectfully traversed for the reasons that follow.

Claim 60 from which these claims depend recites "the instrument is an applicator *for* positioning and fixing *a fixing device* in or around the passage". Claims 77-79 positively recite that the assembly comprises said fixing device and said applicator from claim 60.

Therefore, withdrawal of the rejection is respectfully requested.

Claim Rejections-35 USC §102 and 35 USC §103

Claims 59-61, 63-65, 67-71, 76-79 and 85-89 were rejected under 35 USC §102(e) as being anticipated by TAYLOR U.S. 6,032,672 ("TAYLOR").

Claims 62, 66, 72-75 and 81-84 were rejected under 35 USC §103(a) as being unpatentable over TAYLOR.

Claim 80 was rejected under 35 USC §103(a) as being unpatentable over TAYLOR in view of GIFFORD, III U.S. 5,95,504 ("GIFFORD").

These rejections are traversed for the reasons discussed below.

In following discussion, and claims, the terms distal and proximal are used. Applicant notes that the terms distal and proximal as used in this application are considered with respect to the surgeon. Thus a proximal part is closer to the operator, such as a surgeon, than a distal part. This is explained in the specification at page 16, lines 15-19.

Additionally, in the following discussion, reference will be made to the heart, heart valves, veins and artery connected to the heart etcetera. To illustrate the construction of the natural heart, Applicant has provided a general self explaining drawing of the heart showing all terms used in the Appendix of this response. For the skilled man this is all common knowledge.

The General teachings of TAYLOR

TAYLOR discloses a 'surgical device for imposing a negative pressure to stabilize cardiac tissue during surgery' (See Title).

Referring to column 1 lines 50-51 and figure 4, it is clear that the TAYLOR device is for fixing the position of a portion of the surface of a beating heart.

The TAYLOR device consists of a dome-shaped or semi-spherical housing 8. The circular edge of the housing 8 has a downwardly facing surface 6 provided with several suction ports 2 distributed in circumferential direction of the circular edge surface 6. The suction ports 2 of TAYLOR thus can be considered as 'running in the shape of a loop'. See, e.g., column 4 line 48-55 and figure 2, shown below:

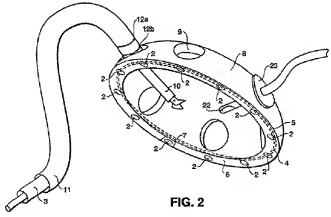

FIG. 2

The suction ports 2 are connected via a pressure conducting channel 4, which in turn is connected to a vacuum source by a vacuum line 3. When negative pressure is imposed, the

suction ports 2 will engage the surface of the heart (column 4 lines 59-60).

The dome-shaped/semi-spherical housing 8 has six (see figure 2) instrument ports 9. As shown in figures 2 and 4, instruments 10, 22 can be inserted through the instrument ports 9. These instrument ports are arranged along and close to the circular edge. Consequently, these instrument ports open, with respect to the loop-shape, in radial direction of the loop (of suction ports 2) and the inserted instrument will extend transverse to the axial direction of the loop (i.e. transverse to the axis perpendicular to the centre of the loop).

TAYLOR discloses in column 5 lines 35-41:

> *"Because the dome portion 8 remains at a fixed distance to the heart, the instrument ports 9 or shaft 11 may have a collar 23 or stop associated therewith such that the distance between the instrument 10 and the heart can be predetermined and fixed by, for example, abutting a stop 12a on the instrument 10 against a stop 12b or collar on the instrument port 9."*

Thus, TAYLOR appears to disclose an instrument stop (stop 12b) provided on the stabilizer (dome portion 8) and a stabilizer stop (stop 12a) provided on the instrument, which stops, in case they contact each other, define the position of the distal end 22 of the instrument with respect to the loop of suction nozzles.

Referring to figure 4, it is noted that this figure is to show the use of the device as is shown in the top view of figure 1 and cross-section of figure 3, which top view and cross section belong to each other (see Column 3 line 55). The discussion of figures 1 + 3 (column 3 line 55 to column 4 line 33) is directly followed by explaining the use with reference to figure 4 (see column 4 line 34). This means that the device in figure 4 also has a closed top (roof) as is shown in the cross section of figure 2, i.e., the embodiment of figures 1, 2 and 3 has a dome shaped housing.

The object of the TAYLOR device is to immobilize a part of the outer surface of the heart with a suction dome so that surgery can be performed with instruments inserted through side ports in said dome. Taking into account that the instruments inserted through the side ports extend about parallel to the surface of the heart these instruments can only perform operations at the surface of the heart and not inside the heart. In order to place the TAYLOR device onto the surface of the heart, the thorax of the patient is to be opened (for example with a so called sternum spreader) so that the heart is exposed for free access of its surface.

The Claimed Invention

The claimed invention, however, comprises a working duct, e.g., item 3 as illustrated in Figures 1 and 2.

A working duct is a tubular element defined by a tubular wall. This tubular element has two opposing ends. One end, which in use is directed to the surgeon, is called the proximal end, the other end, which in use is directed to the patient, is called the distal end. The length of the working duct/tubular element, which defines the axial direction, is typically larger than the diameter of the working duct/tubular element. The distal end and proximal end of a working duct are open so that an instrument can be inserted via the proximal end into the working duct to be advanced towards and through the distal end of the working duct. Afterwards, the instrument can be removed from the working duct in reverse order.

According to the claimed invention, this working duct has distally a loop of one or more suction nozzles, which loop extends in circumferential direction of the working duct.

This working duct according to the invention allows surgery from a distance, i.e. the distal end of the working duct is placed at the location of surgery and the proximal end of the working duct is arranged at a distance from the location of surgery. The surgeon operates the instruments from the proximal end of the working duct. The proximal part of the working duct can extend outside the body of the patient whilst the rest of the duct extends inside the body of the patient, or, in case an operation is performed inside an organ – like the heart – or other body part, the distal part of the working duct extends

inside the organ or body part whilst the rest extends outside the organ or body part. To introduce the working duct into the body of the patient and/or into an organ/body part of the patient, only a small incision is necessary for insertion of the working duct. The working duct of the assembly according to the invention allows performing operations inside the blood stream and assists in minimizing loss of blood.

When the distal end of the working duct has reached the location of surgery, the loop of suction nozzles at the distal end of the working duct allows fixation of the working duct with respect to the precise location of surgery. In this manner the precise location of surgery can be stabilized.

The claimed invention thus provides an assembly allowing minimal invasive surgery (such as placing of implants) on vessels, inside an organ, like the heart, and on heart valves, which surgery is performed from a distance and can be done blindly (i.e. without visual sight of the location of surgery) without needing to open the thorax in case it concerns the heart.

As explained and shown in the present application, the assembly according to the claims allows amongst others:

- Placing (blindly) a heart valve from a distance;
- Placing (blindly) a valve ring from a distance;
- Constricting (blindly) of a valve annulus (for example in case of a leaking heart valve);

- Opening (blindly) the wall of a blood vessel or body cavity;
- Placing (blindly) an anastomotic device for an end-to-side, end-to-end, or side-to-side anastomosis, from a distance;
- Placing (blindly) anastomotic vacuum-adhesive parts and coupling these parts;
- Placing working ducts towards the heart and/or (large) vessels;
- Placing (blindly) from a distance a port or closure in or on the heart or (large) vessel.

None of this is possible with the TAYLOR device. However, it is possible with the claimed assembly, which comprises a working duct having a distal end provided with a loop of suction nozzles.

a. Independent Claims 59, 86-89, 101 and 102

Claim 59

TAYLOR does not disclose a tubular working duct as stabilizer, wherein the working duct is provided with the loop of suction nozzles at the distal end, and wherein the loop extends in circumferential direction of the working duct.

Instead, TAYLOR discloses a dome shaped stabilizer. A dome shaped stabilizer inherently does not have an end, such as a distal end.

As recited in claim 59, the instrument is insertable in the axial direction of the working duct, which axial direction inherently extends perpendicular to the loop of suction nozzles because said loop extends in circumferential direction of the working duct.

According to TAYLOR the instruments are insertable through ports extending about parallel to the loop of suction ports.

Assuming, as is not the case, that, the TAYLOR device of figure 4 might have an open roof (instead of having a closed dome-shaped roof as is disclosed by TAYLOR, see earlier discussion above), it is to be noted that in this assumed situation the TAYLOR device would be a kind of suction ring having an axial height/length much smaller than the diameter. From figure 3, it appears that this axial/length would be at most ¼ of the diameter. As recited in claim 59, a working duct typically has an axial length larger than the diameter. Further, in this assumed situation, TAYLOR does not disclose a stabilizer stop and instrument stop which in contact with each other define unambiguously the position of the head section with respect to the position of the loop shape.

In view of the above discussion, although TAYLOR discloses a dome-shaped stabilizer having an instrument port through which an instrument is insertable, TAYLOR does not

disclose a tubular working duct (which also carries distally the suction nozzles) through which an instrument is insertable.

Thus, TAYLOR fails to anticipate amended claim 59.

TAYLOR, alone or in combination with the cited prior art, also fails to render obvious Claim 59 for the reasons that follow.

By providing a tubular working duct as a stabilizer, which working duct is distally provided with a loop of suction nozzles extending around the distal end of the working duct, it becomes, as explained earlier above, according to the invention possible to stabilize a vascular channel, like a graft vessel all around the circumference of the vascular channel. The working duct can grip the vascular channel from the outside along its circumference in case the vascular channel is inserted into the tubular working duct OR the working duct can grip the vascular channel from the inside along its circumference in case the working duct is inserted into the vascular channel.

The tubular working duct as stabilizer enables the assembly according to the invention being used for fitting heart valve prostheses. In case of heart valve prosthesis and referring to the enclosed general drawing of the heart, the tubular working duct allows accessing the target location (i.e. the valve where the operation is to be carried out) through the right atrium or right ventricle in case the tricuspid valve is the target, through the pulmonary artery or right ventricle in case the

pulmonary valve is the target, through the aorta or left ventricle in case the aortic valve is the target, or through the left atrium or left ventricle in case the mitral valve is the target. The operation thus can be carried out from a distance (through the working duct) and minimally invasive as no large incision is necessary in order to allow the hands of the surgeon to reach the target location. The suction nozzles at the distal end of the tubular working duct allow stabilization of the tubular working duct with respect to the target location. Subsequently the cooperating stops on the stabilizer and instrument allow stabilization of the instrument with respect to the target location.

The claimed invention thus allows stabilizing a vascular channel all around the circumference of the vascular channel. TAYLOR only allows stabilizing the outer surface of the heart not specifically stabilizing a vascular channel. TAYLOR does not disclose or suggest stabilizing a specific vascular channel by gripping the channel itself, and in as far as one might be of the opinion that TAYLOR suggests stabilizing a vascular channel by gripping the channel itself, it is only a part of the wall of the vascular channel which is gripped on the outside from one side (not all around the circumference).

Therefore, it is respectfully submitted that claim 59 is neither anticipated nor rendered obvious over the applied prior art. Consequently Claim 59 is patentable.

Claims 86 - 89

Independent claims 86, 87, 88 and 89 contain all differentiating features as discussed in relation to claim 59 above, also claims 86, 87, 88 and 89 are neither anticipated nor obvious, and consequently patentable. Claims 87-89 are further discussed in detail below.

Claim 87

After having stabilized a vascular channel by gripping it all around its circumference, it is not only of great importance that the instrument can be held steady (by means of stops lying against each other) with respect to the stabilizer in order to perform the operation with great accuracy, but it is also of importance that the head section of the instrument (distally with respect t the surgeon or other doctor) can be positioned with great accuracy with respect to the stabilizer. This is because in practice it will in many situations be very difficult or impossible to grip a very specific location of vascular tissue accurately with the suction nozzles, for example because the specific location is moving like in case of a beating heart. In these situations it is advantageous to grip the vascular channel at a location in the neighborhood of the specific location. In order to allow the head section of the instrument to stay steady at the correct location, one of the stops is slidable along a guide to adjust it into a position desired to be able to keep the

head section stable at the correct location with respect to the vascular channel, i.e. with respect to the loop of suction nozzles. This is also explained in the present application, see specification page 4 line 31 to page 5 line 27 and also page 21 lines 9-22.

TAYLOR does neither teaches nor suggests that one or both of the stops are slidable and subsequently lockable in order to adjust the position of the head of the instrument depending from the circumstances.

The Official Action states at page 4 last 4 lines:

"It is also well known in the art to provide scales on devices in order to determine the position of the device. Examples of such scales are depth-locators on cutters, syringes, and stereotaxic devices. Therefore, it would have been obvious to one having ordinary skill in the art to modify Taylor with a scale….."

However, In this respect it is to be noted, that this still does not make it obvious to modify TAYLOR to have one stop slidable and lockable in order to be able to adjust the position of one of the stops with respect to the part (dome shaped housing or instrument) carrying the stop.

Neither TAYLOR nor the other prior art discloses the guide to extend essentially transverse to the loop of suction

nozzles. Additionally, it is noted that in case TAYLOR would be provided with a guide for a stop according to the invention, that this guide would extend essentially parallel to the surface defined by the loop of suction nozzles.

Claim 88

Neither TAYLOR nor the other prior art discloses that in the stop position the instrument and stabilizer are mechanically prevented from longitudinally moving with respect to each other. TAYLOR discloses in column 5 lines 42-44 that locking means might be provided to lock the instrument with respect to the dome portion, however these locking means are not mechanical but magnetic or suction driven and thus will not reliably prevent longitudinal movement of the instrument with respect to the dome.

Claim 89

Neither TAYLOR nor the other prior art discloses that in the stop position the instrument and stabilizer are mechanically prevented from rotating with respect to each other. TAYLOR discloses in column 5 lines 42-44 that locking means might be provided to lock the instrument with respect to the dome portion, however these locking means are magnetic or suction driven and thus will not prevent rotation of the instrument with respect to the dome. Further these locking means of TAYLOR do not mechanically fix the instrument with respect to the dome portion.

Claim 101

This claim is a combination of independent claim 59 and dependent claim 67. Accordingly, the reasons discussed above relative to claim 59 apply, supplemented with the arguments given below in relative to the features of claim 67.

A tubular working duct which is distally provided with a loop of suction nozzles opening in radial direction of the working duct, is neither disclosed by TAYLOR nor suggested by TAYLOR or other prior art.

Thus, claim 101 is both novel and non-obvious over the prior art.

Claim 102

This claim is a combination of independent claim 59 and dependent claim 66. Accordingly, the reasons discussed above relative to claim 59 apply, supplemented with the arguments given below in relative to the features of claim 66.

A tubular working duct which is distally provided with a loop of suction nozzles opening in axial direction of the working duct, is neither disclosed by TAYLOR nor suggested by TAYLOR or other prior art.

Thus, Claim 102 is both novel and non-obvious in view of the prior art.

Therefore as neither TAYLOR nor other prior art disclose or suggest the features of the independent claims, withdrawal of the rejections is respectfully requested.

b. Dependent Claims

As the independent claims 59, 86, 87, 88 89, 101 and 102 are patentable for the reasons stated above, the dependent claims are patentable. However, several of the dependent claims will be discussed in further detail below, as the features from these claims are believed to even further distinguish the claimed invention over TAYLOR and the other cited prior art.

Claim 90

After having stabilized a vascular channel by gripping it all around its circumference, it is not only of great importance that the instrument can be held steady (by means of stops lying against each other) with respect to the stabilizer in order to perform the operation with great accuracy, but it is also of importance that the head section of the instrument (distally with respect to the surgeon or other doctor) can be positioned with great accuracy with respect to the stabilizer.

This is because, in practice, it will in many situations be very difficult or impossible to grip a very specific location of vascular tissue accurately with the suction nozzles, for example because the specific location is moving like in case of a beating heart. In these situations it is advantageous to grip the vascular channel at a location in the neighborhood of the specific location. In order to allow the head section of the instrument to stay steady at the correct location, one of the stops is slidable along a guide to adjust it into a position desired to be able to keep the head section stable at the correct location with respect to the vascular channel, i.e. with respect to the loop of suction nozzles. This is also explained in the present application, see specification page 4 line 31 to page 5 line 27 and also page 21 lines 9-22.

TAYLOR neither discloses nor suggests that one or both of the stops are slidable and subsequently lockable in order to

adjust the position of the head of the instrument depending from the circumstances.

The Official Action stated on page 4 last 4 lines:

> *"It is also well known in the art to provide scales on devices in order to determine the position of the device. Examples of such scales are depth-locators on cutters, syringes, and stereotaxic devices. Therefore, it would have been obvious to one having ordinary skill in the art to modify Taylor with a scale….."*

In this respect, however, it is to be noted, that this still does not make obvious to modify TAYLOR to have one stop slidable and lockable in order to be able to adjust the position of one of the stops with respect to the part (dome shaped housing or instrument) carrying the stop.

Claim 61

According to claim 61 which is dependent from claim 90 discussed immediately above, the guide (along which one of the stops is slidable) is provided on the stabilizer and the stabilizer and loop of nozzles are firmly linked to each other so that their mutual positions are fixed relative to each other. This means that it is the (instrument) stop provided on the stabilizer which is adjustable for adjusting the position of the

instrument head relative to the loop when the stops contact each other.

Claim 61 allows the stabilizer, once its stop is adjusted, being used with different instruments without a further adjustment of the stop being necessary in between changing the instruments.

As explained earlier, TAYLOR does not disclose or suggest an adjustable stop. On the contrary, TAYLOR only discloses fixed stops. An adjustable stop according to claim 61, in relation to a tubular working channel is also not known or suggested by other prior art. The adjustable stop according to claim 61 in combination with a tubular working duct thus are not only novel but also non-obvious over TAYLOR and other prior art.

Claim 62

According to claim 62 the guide is provided with a scale having a zero point. As already acknowledged in the Office Action, this is not known from TAYLOR.

Referring to the office action, page 4 last 4 lines:

> *"It is also well known in the art to provide scales on devices in order to determine the position of the device. Examples of such scales are depth-locators on cutters, syringes, and stereotaxic devices. Therefore, it would have been obvious to one*

having ordinary skill in the art to modify

Taylor with a scale…..”

Thus, it appears that the position of the Official Action was, assuming claim 59 is anticipated or obvious over TAYLOR, claim 62 is also obvious over TAYLOR in combination with general knowledge. It is however respectfully submitted that this is incorrect.

According to the invention, the scale with zero point serves a complete different purpose than the scales as depth-locators, which are mentioned by the examiner. The scales as depth locators serve the purpose to provide an indication about how far a cutter, syringe or stereotaxic device is inserted or pushed in. The scales according to the invention serve the purpose to know the required degree of adjustment of the stop after having determined/measured the distance from the suction nozzles gripping tissue to the target location where an operation is to be performed. When this distance is for example one cm, the stop must be adjusted to be located one cm below the zero point of the scale. A scale with zero point according to claim 62 is not known from the prior art, neither suggested by the prior art.

Thus the scale according to claim 62 of the invention is in combination with the adjustable stop of claim 59 non-obvious over the prior art.

Claim 64

Neither TAYLOR nor the other prior art discloses or suggests a guide along which one of the stops is adjustable. Consequently also the location of such a guide is not known or suggested by TAYLOR or other prior art.

Claim 66

According to claim 66, the stabilizer comprises one or more suction nozzles opening in the axial direction with respect to the loop shape/working duct, such as shown in figures 12 and 19 of the application.

As acknowledged in the Office Action (page 4 at about the middle), this is not disclosed by TAYLOR.

Advantages of 'axial suction nozzles opening in axial direction' on the distal end of a tubular working duct are already given in the original application, see amongst others P9 L6-12: it is in particular advantageous for fitting the stabilizer to the wall of one of the cardiac chambers, or around the mitral valve or tricuspid valve, where the suction nozzles can than adhere by suction to the heart atrium tissue. Referring to the enclosed general drawing of the heart, it is in addition noted that the mitral valve and tricuspid valve lie for the surgeon, who comes through the left atrium and right atrium

respectively, at the bottom of a dilated hollow space, the left and right atrium respectively. In these cases, the tissue surrounding the valve to be operated will extend transversely to the longitudinal direction of the working duct. Axially oriented suction nozzles at the distal end of the working duct allow reliable gripping of the annulus (i.e. the tissue from where the natural valve leaves origin) of the respective valve. Similar situations might occur in case of a dilated aorta (providing access to the aortic valve) or in case of a dilated pulmonary artery (providing access to the pulmonary valve.

It is respectfully noted that the drawing of the heart might suggest that the mitral valve (and tricuspid valve) extends all over the separation between the left atrium and left ventricle (respectively the right atrium and right ventricle), however, as the skilled man knows, in reality there is, between the left atrium and left ventricle (respectively right atrium and right ventricle), a wall having a passage in which the mitral valve (or tricuspid valve) is arranged. These walls, as part of the valve annulus, provide the above mentioned tissue extending transverse to the working duct.

Such axial suction nozzles opening in the axial direction of the working duct are neither known from TAYLOR nor from other prior art. Such axial suction nozzles are also not suggested by TAYLOR or other prior art.

The axial suction nozzles according to claim 66 in combination with a tubular working duct thus are not only novel but also non-obvious over TAYLOR and other prior art.

Claim 92

Claim 92 depends from claim 66 discussed just above. According to this claim 92 the axial suction nozzles comprise one or more inclined suction nozzles opening outwards obliquely with respect to the axial direction of working duct. It is thus possible that all axial suction nozzles open obliquely or that part of the axial nozzles open exactly in axial direction whilst others open in obliquely axial direction.

Referring to the specification page 9, lines 28-33, axial suction nozzles opening obliquely outwards are especially advantageous in case of use for operations on the mitral valve or tricuspid valve. This provides a better grip.

Axial suction nozzles opening in obliquely axial direction of the working duct are neither known from TAYLOR nor from other prior art. Such obliquely axial suction nozzles are also not suggested by TAYLOR or other prior art.

The obliquely axial suction nozzles according to claim 92, in combination with a working duct, thus are novel as well as non-obvious over TAYLOR as well as other prior art.

Claim 67

According to claim 67, the working duct is distally provided with one or more radial suction nozzles opening in the radial direction of working duct, such as shown in figures 11 and 2 of the application.

Advantages of 'radial suction nozzles opening in radial direction of the working duct' on the distal end of a tubular working duct are already given (specification page 9, lines 13-27). In case of a procedure for an end-to-side (= ETS, i.e. the graft vessel to be attached is attached with its end is attached to the side of another vessel) anastomosis or an end-to-end (=ETE, i.e. the graft vessel to be attached with its end is attached to the end of another vessel), the graft vessel will extending coaxially with the working duct, so that these radial nozzles are able to grip the inner or outer wall of the graft vessel by suctioning. After establishing the ETS or ETE anastomosis, the attachment can simply be released by switching off or disconnecting the suctioning source. In case of a procedure in a relatively narrow channel, like an operation on an aortic valve in the ascending aorta, these radial nozzles enable to suck tightly the blood vessel tissue of the aorta for stabilizing the working duct inside the aorta and (consequently the instrument of the claimed assembly) with respect to the aortic valve region.

Such radial suction nozzles opening in the radial direction of the loop of the working duct are neither known from TAYLOR nor from other prior art. Such radial suction nozzles are also not suggested by the prior art.

The radial suction nozzles according to claim 67, in combination with a tubular working duct, thus are not only novel but also non-obvious over TAYLOR and other prior art.

Claim 68

The arguments given above in relation to claim 92, apply mutatis mutandis to claim 68 as well.

Claim 68 depends from claim 67 discussed just above. According to this claim 68 the radial suction nozzles comprise one or more inclined suction nozzles opening outwards obliquely with respect to the axial direction of the working duct.

Referring to the application at specification page 9 lines 28-33, radial suction nozzles opening obliquely outwards are especially advantageous in case of use for operations on the mitral valve or tricuspid valve. This provides a better grip.

Radial suction nozzles opening in obliquely axial direction of the working duct are neither known from TAYLOR nor from other prior art. Such obliquely radial suction nozzles are also not suggested by TAYLOR or other prior art.

The obliquely radial suction nozzles according to claim 68, in combination with a working duct, thus are novel as well as non-obvious over TAYLOR as well as other prior art.

Claim 69

Claim 69 depends from claim 67. According to claim 69 the radial suction nozzles open in radially inward direction.

Advantages of this embodiment are described at specification page 61, line 30 to page 62 line 2: It allows engaging a wall of (vessel) tissue from the outside. For example in case of an aortic valve operation this embodiment makes it possible to suck a vessel tightly from the outside around its complete or partial circumference. As the stabilizer is kept outside the vessel, it will be clear that inside the vessel no damage can be done to the endothelium. This is also advantageous in making connections between vessels or between vessels and grafts.

Such radially inward suction nozzles opening in the radially inward direction of the working duct are neither known from TAYLOR nor from other prior art. Such radially inward suction nozzles are also not suggested by the prior art.

The radially inward suction nozzles according to claim 69, in combination with a tubular working duct, thus are not only novel but also non-obvious over TAYLOR and other prior art.

Claim 91

Claim 91 depends from claim 67. According to claim 91 the radial suction nozzles open in radially outward direction.

The Advantages of this embodiment follow from page 9 lines 13-21 and page 19 lines 16-20 and figures 1-2 of the present application. The radially outward suction nozzles allow gripping a vessel, into which the working duct is inserted, from the inside by suctioning the suction nozzles tightly against the inner wall of said vessel.

Such radially outward suction nozzles opening in the radially outward direction of the working duct are neither known from TAYLOR nor from other prior art. Such radially outward suction nozzles are also not suggested by the prior art.

The radially outward suction nozzles according to claim 91, in combination with a tubular working duct, thus are not only novel but also non-obvious over TAYLOR and other prior art.

Claim 73

Claim 73 claims that the part of the stabilizer comprising the one or more suction nozzles can be uncoupled from the rest of the stabilizer.

Referring to page 10 L3-13 of WO 03/082121 this is very useful in case after the intervention the suction nozzle can not easily be removed or in case it is to be left behind as implant.

The implant can be attached to tissue by means of for example sutures, adhesive, staples, clips etc.

TAYLOR does not disclose or suggest a tubular working duct having suction nozzles which can be uncoupled. Neither is this known from or suggested by other prior art. Therefore claim 73 is novel and non-obvious over TAYLOR and other prior art.

Claims 74-75

Claims 74 and 75 are directed to a working duct having distally suction nozzles provided on at least two segments which are adjustable in radial direction of the loop by an adjustment mechanism in order to constrict or widen the passage in or around which the working duct is arranged during use.

Referring to page 10 line 14 to page 15, line 8 of the present application, specifically page 10 lines 20-30 - when a so called ring prosthesis is to be fixed in order to repair a - leaking valve - leaking valves usually are caused by the passage of the valve being to wide -. Suction nozzles arranged on radially adjustable segments are also very useful (page 10 line 30 to page 11, line 4) for fitting an ordinary valve prosthesis in order to make the passage larger in case the passage is somewhat too small for accommodating the valve prosthesis or in order to make the passage smaller in case the passage is somewhat too large for accommodating the valve prosthesis.

TAYLOR only discloses a scissors like device having two suction feet for suctioning tight onto the outer surface of a heart in order to spread the tissue in between the suction feet. By spreading two straight parallel suction feet, this tissue is kept taught so that movement of the tissue is counteracted. This scissors like device is shown in figures 5 and 9 of TAYLOR. This scissors like device of TAYLOR has nothing to do with the dome shaped stabilizer of TAYLOR except that both are attached by suctioning on the outer surface of the heart.

Nothing in TAYLOR hints in the direction of any operation performed inside a vessel, in which operations it might be useful to be able to widen or restrict a more or less round passage.

Radially adjustable suction nozzles on the distal end of a tubular working duct are neither known from TAYLOR nor from other prior art. Such radially adjustable suction nozzles are also not suggested by the prior art.

The radially adjustable suction nozzles according to claims 74 and 75 in combination with a tubular working duct thus are not only novel but also non-obvious over TAYLOR and other prior art.

Claim 93

According to claim 93, there is provided a sealing ring at the distal bottom end of the working duct. Such a sealing ring

improves the sealing when suctioning surrounding tissue tight against the working duct.

Neither TAYLOR, nor any other prior art discloses or suggests such a sealing ring. Therefore claim 93 is novel and non-obvious over TAYLOR and other prior art.

Claim 97

According to claim 97, the loop of suction nozzles is a saddle shaped loop. Referring to figure 18 of the application, this provides a very good grip on the side of a vessel, for example in case of an ETS anastomosis.

Neither TAYLOR, nor any other prior art discloses such a saddle shaped loop of suction nozzles. Therefore claim 97 is novel and non-obvious over TAYLOR and other prior art.

Claims 98 and 99

According to these claims a flange is provided at the distal end of the working duct. This is advantageous for stabilizing the working duct on a vessel.

Claims 100-102

According to claims 98 and 99 the part of the stabilizer comprising suction nozzles is provided with an adhesive or can be provided with an adhesive via an adhesive feed, respectively.

As described extensively in the present application (see inter alia page 34 lines 3-15 and page 54 line 9 to page 55), this provides great advantages when the suction nozzles are to be left behind as an implant. The combination of suction nozzles and adhesive allows obtaining a very reliable and solid attachment of the implant with the tissue. The suction nozzle keeps the implant and tissue strongly against each other while the adhesive is curing.

According to claim 102, the suction nozzles can be used to apply the adhesive.

Neither TAYLOR, nor any other prior art discloses such a combination of suction nozzles and adhesive. Therefore claim 100, 101 and 102 are novel and non-obvious over TAYLOR and other prior art.

Claim 103

According to claim 103 the adhesive nozzles comprise compartments. This allows the adhesive to be located inside the compartments when curing against the vessel. This in turn prevents the adhesive from becoming sucked in by the suction nozzles, which might cause disappearing of adhesive and blockage of the suction nozzles.

Claim 104

According to this claim the flange is provided with adhesive. This creates a very solid connection to the wall of tissue.

Claim 108

This claim requires that a suction passage formed in the interior of the wall of the working duct extends from the suction nozzles up to a proximal part of the working duct. In as far as TAYLOR discloses a suction passage formed in the wall of the dome, it does not disclose or suggests that this suction passage extends to the upper part of the dome. The suction passage of claim 108 keeps the internal lumen of the working duct free and allows the working duct to be inserted into a humen body over almost its entire length without being hindered by the suction line.

This claim 108 is therefore clearly novel and non-obvious over TAYLOR and other prior art.

Claim 109

Such a closure allows closing the passage of a part uncoupled from the stabilizer. In this way a so called port is established which might be opened again in case a subsequent operation or inspection might be necessary.

Claims 111 and 112

These claims require additionally that one or more valves - allowing passage of the instrument - are arranged in the working duct. These valves prevent leakage of blood as follows from page 50, lines 27-28 of the application. TAYLOR does not disclose or suggest such valves.

These claims therefore are clearly novel and non-obvious over TAYLOR and other prior art.

Claims 116 and 117

These claims require the working duct to be curved or bendable/flexible, respectively. This facilitates advancing the working duct along a curved path, for example a curved vessel.

These claims therefore are clearly novel and non-obvious over TAYLOR and other prior art.

Charge the fee of $728 for the 28 additional claims of any type added herewith, to our credit card.

Charge the fee of $220 for the two additional independent claims added herewith, to our credit card.

Conclusion

In view of the amendment to the claims and the foregoing remarks, this application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our credit card which is being paid online simultaneously herewith for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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APPENDIX:

The Appendix includes the following item(s):

-Drawing of the heart, as understood by those skilled in the art.

Normal Heart